REMARKS

In response to the Office Communication of December 29, 2005, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132 and 37 CFR 1.114.

Claim Status/Support for Amendments

Claim 39 has been amended. Claims 2-38 were cancelled in a previous response (filed on December 10, 2004). Claims 39-46 are withdrawn from consideration. It is understood that claims 39-46, drawn to the non-elected invention, will remain pending, albeit withdrawn from consideration on the merits at this time. If the examined claim of the Group I invention is deemed to be allowable, rejoinder of the remaining claims (39-46) in accordance with the decision in *In re Ochiai* is respectfully requested; since the remaining claims (39-46) are limited to the use of the biopolymer markers of claim 1 (the examined claim of the elected Group I invention).

Claim 1 is currently under examination. Claims 1 and 39-46 remain pending in the instant application.

No new matter has been added by the amendment to the specification made herein.

The paragraph at page 24 has been amended to correct a typographical error (luymph to lymph).

No new matter has been added by the amendment to claim 39 made herein.

Claim 39 was amended to provide proper antecedent basis for the term "biopolymer marker". The word "marker" was inadvertently deleted by typographical error.

Request for Rejoining of Claims

Considering that claims 39-46 are limited to the use of SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3 a search of these claims would encompass these specific sequences. The instant application is related in claim format to several other applications, both pending and issued, of which serial number 09/846,352 is exemplary. In an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner consider rejoining claims 39-46 in the instant application, which are currently drawn to non-elected Groups, with claim 1 of the elected Group under the decision in *In re Ochiai* (MPEP 2116.01), upon the Examiner's determination that claim 1 of the elected invention is allowable and in light of the overlapping search. If the biopolymer markers of SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3 are found to be novel, methods and kits limited to their use should also be found novel.

Declaration under 37 CFR 1.132

The Examiner entered the Response filed on December 1, 2005. However, in the Advisory Action mailed on December 29, 2005 the Examiner indicated that the request for reconsideration has been considered but does not place the application in condition for allowance because the data provided (drawings/figures) allegedly does not show clear differential expression of the claimed sequences (SEQ ID NOS:1-3). Thus, the Final Rejection has been maintained.

Applicants strongly disagree with the Examiner's determination and assert that the figures (Figures 1-5, as originally filed; Figures 1 and 4, as attached to the declaration filed herewith) do provide clear differential expression of the claimed sequences (SEQ ID NOS:1-3).

In order to illustrate this point, Applicants provide the attached Declaration (with two figures and a table) under 37 CFR 1.132. The figures (Figures 1 and 4) attached to the declaration were previously provided to the Examiner in an e-mail dated December 14, 2005; however these figures were never formally entered into the prosecution record.

The first figure attached to the declaration filed herewith is entitled "DEAE 1(Elution) Normal vs. Diabetes Type II" and represents Figure 1 as originally filed. This figure was produced

by scanning the original photograph of the gel. The claimed SEQ ID NOS:1 and 2 were obtained from samples analyzed in the gel shown in Figure 1.

At page 46, lines 8-11 of the instant specification as originally filed, SEQ ID NO:1 is identified as a fragment of the complement C3f precursor protein having a molecular weight of about 1212 daltons (1211.67 daltons). Figure 2, as originally filed, shows the characteristic mass spectral profile of SEQ ID NO:1 (see top left of figure for band number analyzed, D1(E)C3-2 and see top right of figure for molecular weight of the exemplified ion, 1211). Band 3-2, identified in lane 1 of the gel shown in Figure 1, is clearly labeled as containing complement C3f. Thus, it can be ascertained that the claimed SEQ ID NO:1 is a fragment of the complement C3f precursor protein weighing about 1212 daltons obtained from Band 3-2 of the gel as shown in Figure 1. Band 3-2 is immediately evident in all four normal samples (lanes 1-4, as read from the left, marked by circles) and clearly absent in all five diabetes Type II samples (lanes 5-9, marked by squares).

At page 46, lines 11-13 of the instant specification as originally filed, SEQ ID NO:2 is identified as a fragment of the complement C3 precursor protein having a molecular weight of about 2173 daltons (2172.99 daltons). Figure 3, as originally filed, shows the characteristic mass spectral profile of SEQ ID NO:2 (see

top left of figure for band number analyzed, D1(E)C3-2 and see bottom right of figure for molecular weight of the exemplified ion, 2173). Band 3-2, identified in lane 1 of the gel shown in Figure 1, is clearly labeled as containing complement component 3 precursor. Thus, it can be ascertained that the claimed SEQ ID NO:2 is a fragment of the complement C3 precursor protein weighing about 2173 daltons obtained from Band 3-2 of the gel as shown in Figure 1. Band 3-2 is immediately evident in all four normal samples (lanes 1-4, as read from the left, marked by circles) and clearly absent in all five diabetes Type II samples (lanes 5-9, marked by squares).

No new matter has been added; Figure 1, as attached to the declaration filed herewith, is simply a clearer copy of Figure 1 as originally filed and is provided to clarify the presence and differential expression of the claimed biopolymer markers (SEQ ID NOS:1 and 2). The gel shown in the figure does not represent new experimentation; the figure shows a clearer image of the original gel made at the time that the experiments described in the instant specification were first carried out.

The second figure attached to the declaration filed herewith is entitled "HiQ3 (scrub) Normal vs. Diabetes Type II" and represents Figure 4 as originally filed. This figure was also produced by scanning the original photograph of the gel. The

claimed SEQ ID NO: 3 was obtained from samples analyzed in the gel shown in Figure 4.

At page 46, lines 13-15 of the instant specification as originally filed, SEQ ID NO:3 is identified as a fragment of the complement C3 precursor protein having a molecular weight of about 1191 daltons (1190.6210 daltons). Figure 5, as originally filed, shows the characteristic mass spectral profile of SEQ ID NO:3 (see top left of figure for band number analyzed, Q (SCRUB)S2 and see top right of figure for molecular weight of the exemplified ion, 1190.60). Band 2, identified in lane 10 of the gel shown in Figure 4, is clearly labeled as containing complement component 3 precursor. Thus, it can be ascertained that the claimed SEQ ID NO:3 is a fragment of the complement C3 precursor protein weighing about 1191 daltons obtained from Band 2 of the gel as shown in Figure 4. Band 2 is immediately evident in all four normal samples (lanes 7-10, as read from the left) and clearly absent in all five diabetes Type II samples (lanes 2-6).

No new matter has been added; Figure 4, as attached to the declaration filed herewith, is simply a clearer copy of Figure 4 as originally filed and is provided to clarify the presence and differential expression of one of the claimed biopolymer markers (SEQ ID NO:3). The gel shown in the figure does not represent new experimentation; the figure shows a clearer image of the original

gel made at the time that the experiments described in the instant specification were first carried out.

The table attached to the declaration filed herewith is a partial listing of markers identified by the instant inventors; including the currently claimed markers, SEQ ID NOS:1-3 (see experiments 9, 10 and 17; marked by *). Each peptide marker in the table is described using five main categories. For example, one of the currently claimed markers, SEQ ID NO:2, was obtained from Band 3 of the gel using DEAE 1 Elution chromatography as the preparatory step to mass spectrometric analysis, identified during experiment 17 as a fragment of complement C3 precursor weighing about 2172 daltons and was found to be present in normal samples during comparison of normal samples versus Type II diabetes samples. It is noted that instantly claimed SEQ ID NO:1 was also identified in Band 5 of the gel shown in Figure 4. No new matter has been added by the disclosure of the table. The data summarized in the table does not represent new experimentation; the table shows the data which was collected at the time that the experiments described in the instant specification were first carried out.

Accordingly, it is established that the figures(Figures 1-5, as originally filed and Figures 1 and 4, as attached to the declaration filed herewith) show that the claimed peptides (SEQ ID NOS:1-3) are present in samples obtained from patients

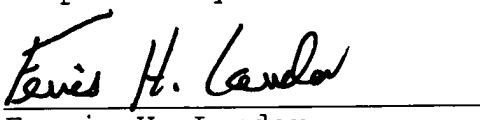
determined to be normal with regard to Type II diabetes and absent from samples obtained from Type II diabetes patients. Thus, contrary to the Examiner's determination, the figures do show differential expression of the claimed sequences (SEQ ID NOS:1-3).

Accordingly, Applicants respectfully request that the Final Rejection now be withdrawn.

CONCLUSION

In light of the foregoing remarks, amendment to the specification and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



Ferris H. Lander
Registration # 43, 377

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)

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